

CURRICULUM VITAE

Name:

Terri M. King, Ph.D.

Present Title:

Assistant Professor

Address:

The University of Texas - Houston Medical School

Children's Learning Institute Department of Pediatrics 7000 Fannin, Suite 2300 Houston, Texas 77030

Phone:

713-500-3738

E-Mail:

Terri.M.King@uth.tmc.edu

Citizenship:

U.S.

Undergraduate Education:

9/1983 - 5/1985

University of Texas at San Antonio

San Antonio, Texas

Applied Mathematics

9/1985 - 5/1988

University of Texas

Austin, Texas

Bachelor of Science

Zoology

Graduate Education:

9/1988 - 5/1989

Georgetown University

Washington, D.C.

Master of Science

Biostatistics/Epidemiology

9/1989 - 12/1993

Johns Hopkins University

Doctor of Philosophy

Human Genetics/Genetic

Epidemiology

9/1996 - 5/1998

Rice University

Mathematical Statistics

Postgraduate Training:

9/1993 - 6/1995

Post-doctoral Fellowship

The University of Texas M.D. Anderson Cancer Center

Supervisor: Christopher I. Amos, Ph.D.

5/2005 - 2/2007

PhD Medical Genetics Fellowship University of Texas HSC – Houston

Academic Appointments:

2005 - Present

Assistant Professor

Department of Pediatrics

The University of Texas - Houston Medical School

1997 - Present

Associate Member

U.T. Graduate School of Biomedical Sciences

2001 - 2005 Assistant Professor

Department of Internal Medicine

The University of Texas - Houston Medical School

1996 - 2001 Assistant Professor (NTRA)

Department of Epidemiology

U.T. M. D. Anderson Cancer Center, Houston, Texas

1999 - 2001 Director, Pharmacogenetics and Epidemiology

Genometrix, Inc., The Woodlands, Texas

Certifications and Licensures:

PhD Medical Genetics, American Board of Medical Genetics, 2007

Professional Organizations:

American Society of Human Genetics International Genetic Epidemiology Society

Committee: Ethics, Legal and Social Issues 1999-2003

Honors and Awards:

National Cancer Institute, Preventive Oncology Academic Award (K-07), 1996-2001.

University Cancer Foundation, <u>Cancer Prevention Post-Doctoral Fellowship</u>, Department of Epidemiology, The University of Texas M. D. Anderson Cancer Center, 1993-1995.

National Cancer Institute, <u>Cancer Prevention Education Fellowship</u>, Department of Epidemiology The University of Texas M. D. Anderson Cancer Center, 9/93 -11/93.

National Cancer Institute, <u>Cancer Epidemiology Institutional Fellowship</u>, Department of Epidemiology, The Johns Hopkins University School of Hygiene and Public Health, 1990-1993

<u>Scholarship</u>, Department of Epidemiology, The Johns Hopkins University School of Hygiene and Public Health, 1989-1990

Service on National Grant Review Panels, Study Sections Committees:

| 6/2008 | Committee Member, SBIR Study Section ZRG HPE-E (10) |
|---------|-----------------------------------------------------|
| 4/2008 | Committee Member, SEP NHLBI ZHL1 CCT-R (C1-C4) |
| 2/2008 | Committee Member, SBIR Study Section ZRG HPE-E (10) |
| 6/2007 | Committee Member, SBIR Study Section ZRG HPE-E (10) |
| 3/2007 | Committee Member, SBIR Study Section ZRG HPE-E (10) |
| 12/2006 | Committee Member, SEP NHLBI ZHL1 CSR-L F1 |
| 3/2006 | Committee Member, SEP NHLBI ZHL1 CSR-L M1 |
| 9/2005 | Committee Member, SEP NHLBI |
| 6/2003 | Committee Member, K-23 Panel, NHLBI |
| 2/2003 | Committee Member, SEP NHLBI |
| 3/2001 | Committee Member, SEP NHLBI |
| 2/2001 | Committee Member, SEP NHLBI |
| | |

Service on The University of Texas-Houston Health Science Medical School Committees:

9/2008 - Present Committee Member, Intellectual Property Committee

9/2008 – Present Committee Member, Committee for the Protection of Human Subjects

4/2001 – Now Committee Member, SAC, CTRC

9/2002 - 8/2005 Graduate School Education Committee

Service to the Community:

3/1996 – 3/2001 Board of Directors, St. Anne's Foundation

Sponsorship of Candidates for Postgraduate Degree:

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|------------------|--------------------------------------------|
| 5/2008 – 5/2009 | S.M.S, Committee Member, Jennifer Fowler |
| 5/2008 - 5/2009 | S.M.S, Committee Member, Sarah Colosimo |
| 5/2007 - 5/2008 | S.M.S., Committee Member, Lauren McNair |
| 5/2007 - 5/2008 | S.M.S., Committee Member, Blair Stevens |
| 1/2007 - 5/2007 | S.M.S., Chair, Cathy Sullivan |
| 12/2006 - 5/2007 | S.M.S., Committee Member, Catherine Tipps |
| 11/2006 - 5/2007 | S.M.S., Committee Member, Alyssa Knisley |
| 10/2007 - 5/2007 | S.M.S., Committee Member, Amy Stanford |
| 7/2004 - 12/2006 | Ph.D., Committee Member, Lisa Vincent |
| 10/2005 - 5/2006 | S.M.S., Committee Member, Jennifer Sherril |
| 10/2005 - 5/2006 | S.M.S., Committee Member, Julia Wynn |
| 10/2005 - 5/2006 | S.M.S., Committee Member, Marianna Horz |
| 10/2004 - 5/2005 | S.M.S., Committee Member, Tamara Soloman |
| 10/2004 - 5/2005 | S.M.S., Committee Member, Cynthia Trotter |
| 10/2004 - 5/2005 | S.M.S., Committee Member, Jennifer LeMoine |
| 10/2003 - 5/2004 | S.M.S., Committee Member, Alice Schindler |
| 10/2003 - 5/2004 | S.M.S., Committee Member, Carol Linsner |
| 10/2003 - 5/2004 | S.M.S., Committee Member, Colleen Buechner |

Teaching Responsibilities:

2007 Population Genetics Lecture, Medical Genetics Lecture, MSII Curriculum

2005 – 2007 Medical Genetics Small Groups, MSII Curriculum

Grant Support:

Scaling Up a Language & Literacy Professional Development Program at the Prekindergarten Level, R305W020002, DOE, Susan Landry, Ph.D., Principal Investigator, October, 2002 to September, 2007, \$723,596/ year direct costs, **1.2 PM**

Evaluation of Prekindergarten Curricula in Head Start and Public School Settings, R305J020014, DOE, Susan Landry, PhD, Principal Investigator, July, 2002 to July, 2007, \$311,213/ year direct costs, **1.2 PM**

Early Childhood School Readiness Program: Texas Early Education Model (TEEM), 61044017110001, Texas Education Agency, Susan Landry, PhD, Principal Investigator, September, 2005 to June 2010, \$6,736,112/ year direct costs, **2.4 PM**

Spina Bifida: Cognitive and Neurobiological Variability, P01 HD35946, NICHD, NIH, Jack M. Fletcher Ph.D., Principal Investigator, Terri M. King co-Principal Investigator, Core C (J.M. Fletcher, P.I.), March, 1998 to October, 2007, **6.0 PM**

Genetic Studies of Clubfoot (ITEV), R01 HD043342-01, NIH, Jacqueline Hecht, Ph.D., Principal Investigator, September, 2006 to October, 2007, \$219,576/ year direct costs **0.60 PM**

Gene Polymorphisms Predisposing to Infectious Diarrhea, R01, Pablo Okhuysen, M.D. Principal Investigator, Terri M. King, Ph.D, Co-Investigator, October, 2003 to August, 2005 0.60 PM

University General Clinical Center, L. Maximilian Buja, M.D., Principal Investigator, March, 2001 to August, 2005 **2.4 PM**

Teamwork and Error in Neonatal Intensive Care, Agency for Healthcare Research and Quality, Eric Thomas, MD, MPH, Terri M. King, Ph.D, Co-Investigator, \$677,076, September, 2000- August, 2003 0.6 PM.

Genetics of Malignant Histiocytomas in the Flat-Coated Retriever, American Kennel Club 1817, Terri M. King, Ph.D., Principal Investigator, September, 1999, September, 2002, \$24,064/yr.

Genetic Variation in Radiation-Induced Normal Tissue Damage, PO1 CA06294, Kie-Kian, M.D., Ph.D., Principal Investigator, Terri M. King, Ph.D. Co-Investigator, April, 1997 to March, 2002, \$133,872/yr.

Development of Robust Genetic Linkage Tests, RO1 GM52607, NIH, Christopher I. Amos, Ph.D., Principal Investigator, Terri M. King, Ph.D., Co-Investigator, May, 1995 to April, 1998 \$90,851/yr, Total \$272,555

Cancer Susceptibility in Former Smokers, U19CA68437, Margaret R. Spitz, M.D., M.P.H., Terri M. King, Ph.D., Co-Investigator, 07/01/95 - 06/30/00, \$355,551/yr., Total \$1,066,654

Genetic Epidemiology of Bleomycin Sensitivity, RO3 CA69089A, NIH, Christopher I. Amos, Ph.D., Principal Investigator, Terri M. King, Ph.D., Co-Principal Investigator, 03/01/96 - 02/28/97, \$49,978/yr., Total \$49,978

Genetic Basis of Radiation Induced Fibrosis, RO1 CA64193, NIH, Elizabeth Travis, Ph.D., Principal Investigator, Terri M. King, Ph.D., Co-Investigator, 07/01/96 - 06/30/00, \$35,839/yr., Total \$143,357

Preventive Oncology Academic Award, KO7 CA67960A, NIH, Terri M. King, Ph.D., Principal Investigator, 07/01/96 - 06/30/01, \$76,396/yr., Total \$381,981

Publications:

A. Refereed Original Articles in Journals

- 1. Davidson CM, Northrup H, King TM, Fletcher JM, Townsend I, Tyerman GH, Au KS. Genes in glucose metabolism and association with spina bifida. Reprod Sci 2008 Jan. 15(1):51-8.
- 2. Wynn J, King TM, Gambello MH, Waller DK, Hecht JH. Mortality in achondroplasia study: a 42-year follow-up. Am J Med Genet A. 2007 Nov 143(21):2502-11.
- 3. King TM, Au K-S, Kirkpatrick TJ, Fletcher JM, Copeland K, Townsend I, Villareal G, Tyerman GH, Northrup H. BRCA1 polymorphic alleles show association with lesion location in spina bifida patients. Annals of Human Genetics Ann Hum Genet. 2007 Nov;71(Pt 6):719-28.

- 4. Au K-S, Williams At, Roach ES, Batchelor L, Sparagana S, Wheless JW, Baumgartner J, Roa BB, Wilson C, Smith TK, Cheung MYC, Whittemore VH, **King TM**, Northrup H. Genotype/Phenotype correlation using mutational analysis of the TSC1 and TSC2 genes in 354 individuals referred for a diagnosis of tuberous sclerosis. Genetics in Medicine Genet Med. 2007 Feb;9(2):88-100.
- 5. King BR, King TM, McCans K, Foster RL. Pediatric and neonatal transport teams with and without a physician: A comparison of outcomes and interventions. Pediatric Emergency Care, Pediatr Emerg Care. 2007 Feb;23(2):77-82.
- Daiger SP, Shankar SP, Schindler AB, Sullivan LS, Browne SJ, King TM, Daw EW, Stone EM, Heckenlively JR. Genetic factors modifying clinical expression of autosomal dominant RP. Adv Exp Med Biol 2006; 572:3-8.
- 7. Leichman JG, Aguilar D, King TM, Vlada A, Reyes M, Taegtmeyer H. An Association of Plasma Free Fatty Acids and Left Ventricular Diastolic Function in Patients with Clinically Severe Obesity. Am. J Clin. Nut. 2006; 84(2):336-41.
- 8. Leichman JG, Aguilar D, King TM, Vlada A, Reyes M, Taegtmeyer H. An Association of Plasma Free Fatty Acids and Left Ventricular Diastolic Function in Patients with Clinically Severe Obesity. Am. J Clin. Nut. 2006; 84(2):336-41.
- 9. Pannu H, Kim D, Guo D, King TM, Van Ginhoven, G, Chin T, Chang K, Qi Y, Shete S, Milewicz DMM. Role of *MMP2* and *MMP9* Polymorphisms in Sporadic Intracranial Aneurysms. J. Neurosurg 2006 105(3):418-23.
- 10. Mc Ardle PF, Pollin TI, O'Connell JR, Sorkin JD, Agarwala R, Schäffer AA, Streeten EA, King TM, Shuldiner AR, Mitchell BD. Does having children extend lifespan? A genealogical study of parity and longevity in the Amish. J Gerontol A Biol Sci Med Sci. 2006 Feb;61(2):190-5.
- 11. Au, K-S, Northrup H, Kirkpatrick TJ, Volcik KA, Fletcher JM, Townsend IT, Blanton SH, Tyerman GH, Villarreal G, King TM. Promoter genotype of the platelet-derived growth factor receptor- α gene shows population stratification but not association with spina bifida meningomyelocele. Am J Med Genet A 2005 139A(3):194-198.
- 12 Shaw A, Vaporciyan A, Wu X, King TM, Dickey B, Spitz M, Putnam B. Inflammatory gene polymorphisms influence risk of postoperative morbidity after lung resection. Annals Thoracic Surg 2005 May 79(5):1704-10.
- 13. Ahn C, King TM, Lee K, Kang, S-H. DNA pooling as a tool for case-control association studies of complex traits. Genomics & Informatics 2005 3(1):1-7
- Boccalandro C, de Mattia F, Guo DC, Xue Li, Orlander P, King TM, Gupta P, Deen PMT, Lavis VR, Milewicz DM. Characterization of an Aquaprorin-2 water channel gene causing partial nephrogenic diabetes insipidus in a Mexican family. J Am Soc Nephrol 2004 May 15(5): 1223-31.
- 15. King TM. Using Simultaneous Equation Modeling for Defining Complex Phenotypes. BMC Genetics 2003 Dec 31; 4 Suppl 1:S10.
- 16. Jiang ZD, Okhuysen P, Guo DC, He RM, King TM, DuPont HL, Milewicz DM. Genetic Susceptibility to Enteroaggregative Escherichia coli Diarrhea Polymorphism in interleukin-8 promoter region. J Infect Dis. 2003 Aug 15;188(4):506-11.
- 17. Frazier-Bowers SA, Cavender AC, King TM, Milewicz DM, D'Souza RN. A Unique Form of Hypodontia Observed in Vietnamese Patients: Clinical and Molecular Analysis. J Med Genet. 2003 Jun;40(6)
- 18. Lai D, **King TM**, Moye LA, Wei Q. Sample size for biomarker studies. More subjects or more measuresments per subject Ann. Epidemiol. 2003 Mar 13(3):204-208.
- 19. Haston CK, Wang M, Dejournett RE, Zhou X, Ni D, Gu X, King TM, Weil MM, Newman RA, Amos CI, Travis EL. Bleomycin hydrolase and a genetic locus within the MHC affect risk for pulmonary fibrosis in mice. Hum Mol Genet 2002 Aug 1;11(16):1855-63
- 20. King TM, Tong L, Pack RJ, Spencer C, Amos CI. Accuracy of family history of cancer as reported by men with prostate cancer. Urology 2002 Apr;59(4):546-50

- 21. Frazier-Bowers SA, Guo DC, Cavender A, Xue L, Evans B, King TM, Milewicz D, D'Souza RN. A novel mutation in human PAX9 causes molar oligodontia. J Dent Res 2002 Feb;81(2):129-33
- 22. Baur MP, Majumder PP, Amos CI, Feingold JI, King TM, Morton NE, Province MA, Spence MA, Thomas DC; IGES-ELSI Committee. International Genetic Epidemiology Society: commentary on Darkness in El Dorado by Patrick Tierney. Genet Epidemiol 2001 Sep;21(2):81-104
- 23. Mitchell BD, Hsueh WC, King TM, Pollin TI, Sorkin J, Agarwala R, Schaffer AA, Shuldiner AR. Heritability of life span in the Old Order Amish. Am J Med Genet 2001 Sep 1;102(4):346-52
- 24. Chase GA, King TM, Oja-Tebbe N, Rybicki BA, Goldin LR. Assessment of estimation procedures for risk and onset hazard with dependent data. Genetic Epidemiology 17 Supplement 1:S97-102, 1999.
- 25. Barnholtz JS, de Andrade M, Page GP, **King TM**, Peterson LE, Amos CI. Assessing linkage of monoamine oxidase B in a genome-wide scan using a univariate variance components approach. Genetic Epidemiology 17 Supplement 1:S49-54, 1999.
- 26. Peterson LE, Barnholtz JS, Page GP, **King TM**, de Andrade M, Amos CI. A genome-wide search for susceptibility genes linked to alcohol dependence. Genetic Epidemology, 17 Supplement 1:S295-300, 1999.
- 27. Page GP, King TM, Barnholtz JS, de Andrade M, Peterson LE, Amos CI. Genome scans for genetic predisposition to alcoholism by use of transmission disequilibrium test analyses. Genetic Epidemiology 17 Supplement 1:S277-281, 1999.
- 28. King **TM**, Barnholtz,, J, Page, GP. Familial analysis of event related potentials. Genetic Epidemiology, 17 Supplement 1:S199-204, 1999.
- 29. Dorsten LE, Hotchkiss L, **King TM**. Effect of Inbreeding on Early Childhood Mortality: Twelve Generations of an Amish Settlement. Demography, 36:263-271, 1999.
- 30. **King TM**, Hursting S, Contois J, Wu X, Spitz MR, Hsu TC. Correspondence re: M.T. Goodman, et al., Effects of beta-carotene and alpha-tocopherol on bleomycin-induced chromosomal damage. Cancer Epidemiol Biomarkers Prev. 7(8): 729, 1998.
- 31. Eeles RA, Durocher F, Edwards S, Teare D, Badzioch M, Hamoudi R, Gill S, Biggs P, Dearnaley D, Ardern-Jones A, Dowe A, Shearer R, McLennan DL, Norman RL, Ghadirian P, Aprikian A, Ford D, Amos C, King TM, The Cancer Research Campaign/British Prostate Group U.K. Familial Prostate Cancer Study Collaborators, Labrie F, Simard J, Narod SA, Easton D and Foules WD. Linkage analysis of chromosome 1q markers in 136 prostate cancer families. Am J Hum Genet. 62:653-658, 1998.
- 32. **King TM** and Wan, Y. Linked markers and age at diagnosis. Genet Epidemiol. 14:821-825, 1997.
- 33. **King TM**, Trizna Z, Wu X, Amos CI, Fueger RH, Fueger JJ, Fritsche HA, Hsu TC, Winn R, Spitz MR, UT M. D. Anderson Clinical Community Oncology Program Network. A clinical trial to evaluate the effect of vitamin C on *in vitro* mutagen sensitivity. Cancer Epidemiol Biomarkers Prev. 6(7):537-542, 1997.
- 34. **King TM**, Beaty TH, Liang KY. Comparison of methods for survival analysis of dependent data. Genet Epidemiol 13(2):139-158, 1996.
- 35. Haston CK, Amos CI, King TM, Travis EL. Inheritance of bleomycin-induced pulmonary fibrosis in the mouse. Cancer Res. 56(11)2596-601, 1996
- 36. Dorsten LE, Hotchkiss L, **King TM**. Consanguineous marriage and early childhood mortality in an Amish settlement. Sociological Focus. 29(2):179-185, 1996.
- 37. **King TM**. Zhu D. Amos CI. Association and linkage with quantitative trait. Genet Epidemiol 12 (6):771-775, 1995.
- 38. Jin X, Wu X, Roth JA, Amos CI, King TM, Branch C, Honn SE, Spitz MR. Higher lung cancer risk for younger African Americans with the Pro/Pro p53 genotype. Carcinogenesis 16(9):2205-2208, 1995.

- 39. Dave BJ, Hopwood VL, King TM, Jiang H, Spitz MR, Pathak S. Genetic susceptibility to lung cancer as determined by lymphocytic chromosome analysis. Cancer Epidemiol Biomarkers Prev 4(7): 743-750, 1995.
- 40. King TM, Zhu D, Amos CI. Association and linkage strategies for a quantitative trait. Genet Epidemiol. 2(6):765-9, 1995.
- 41. Goldin LR, Chase GA, King TM, Badner JA, Gershon ES. Use of exact and adjusted liability scores to detect genes affecting common traits. Genet Epidemiol 12(6):765-769, 1995.
- 42. Spitz MR, Hoque A, Trizna Z, Schantz SP, Amos CI, King TM, Bondy ML, Hong WK, Hsu TC. Mutagen sensitivity as a risk factor for second malignant tumors following malignancies of the upper aerodigestive tract. J Natl Cancer Inst 86(22):1681-1684, 1994.
- 43. King TM. Ovarian cancer and fertility drugs. Cancer Bulletin 46(2):181-184, 1994.
- 44. King TM, Brandt J, Meyers DA. The effect of laboratory or clerical error on presymptomatic risk calculations for Huntington disease: a simulation study. Am J Med Genet 46:154-158, 1993.
- 45 Hamosh A, King TM, Rosenstein BJ, et al. Cystic fibrosis patients bearing both the common missense mutation gly -> Asp at Codon 551 and the delta F508 mutation are clinically indistinguishable from delta F508 homozygotes, expect for decreased risk of meconium ileus. Am J Human Genet 51:245-250, 1992.
- 46. Maestri NE, King TM, Colyer CR, Mellen BC, Chase GA, Meyers DA. Using recombinant chromosomes to map new markers. Genetic Analysis Workshop 7: Issues in Gene Mapping and Detection of Major Gene. MacCluer JW, Chakravarti A, Cox D, Bishop DT, Bale SJ, Skolnick MH (eds) Cytogenet Cell Genet 59:116-118, 1992.

B. Chapters

1. Pollock, Raphael E. (ed) Soft Tissue Sarcomas, American Cancer Society Atlas of Clinical Oncology King, TM Chapter 1: Epidemiology, 1-10, BC Decker Inc, Hamilton, 2002.

C. Presentations

- 1. BRCA1 Mutation Show Associations with Lesion Level Location in Spina Bifida Patients, American Society of Human Genetics, October, 2005
- 2. BRCA1 Mutation Show Associations with Lesion Level Location in Spina Bifida Patients, Spina Bifida Workshop, September, 2005
- 3. Complex Segregation Analysis in Inbred Animal Populations, University of California Davis, May, 2004
- 4. Complex Segregation Analysis in Inbred Populations, Pennsylvania State Medical School, Hershey, Pennsylvania, February, 2004
- 5. Overview of Statistical Genetics, Joint Seminar, Departments of Biology and Mathematics, University of St. Thomas, Houston, Texas, November, 2003
- 6. Segregation Analysis of Cancer in the Flat-Coated Retriever, Canine Health Foundation 3rd Annual Cancer and Canine Conference, Aurora, Ohio, September, 2003
- 7. Evaluation of Genetic Association in Cerebral Aneurysms, Grand Rounds, Department of Internal Medicine, University of Texas - Houston Medical School, August, 2003.
- 8. Exploring the Use of Econometric Models in the Analysis of Longitudinal Genetic Data, Genetic Analysis Workshop, November 11-15, 2002.
- 9. Genetic Epidemiology of Cancer in the Flat-Coated Retriever, Canine Health Foundation 2nd Annual Cancer and Canine Conference, Aurora, Ohio, September, 2002
- 10 Epidemiology of Cancer in the Flat-Coated Retriever, Canine Health Foundation 1st Annual Cancer and Canines Conference, Keystone, Colorado, May 2001

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Terms of the Federalwide Assurance

FEDERALWIDE ASSURANCE (FWA) FOR THE PROTECTION OF HUMAN SUBJECTS

U. S. Department of Health and Human Services (HHS) Office for Human Research Protections (OHRP)

A. TERMS OF THE FEDERALWIDE ASSURANCE (FWA) FOR INSTITUTIONS WITHIN THE UNITED STATES

1. Human Subjects Research Must be Guided by Ethical Principles

All of the Institution's human subjects research activities, regardless of whether the research is subject to federal regulations, will be guided by the ethical principles in: (a) The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, or (b) other appropriate ethical standards recognized by federal departments and agencies that have adopted the Federal Policy for the Protection of Human Subjects, known as the Common Rule.

2. Applicability

These terms apply whenever the Institution becomes engaged in human subjects research conducted or supported* by any federal department or agency that has adopted the Common Rule, unless the research is otherwise exempt from the requirements of the Common Rule or a department or agency conducting or supporting the research determines that the research shall be conducted under a separate assurance. In general, the Institution becomes so engaged whenever (a) the Institution's employees or agents intervene or interact with human subjects for purposes of federally-conducted or –supported research; (b) the Institution's employees or agents obtain individually identifiable private information about human subjects for purposes of federally-conducted or –supported research; or (c) the Institution receives a direct federal award to conduct human subjects research, even where all activities involving human subjects are carried out by a subcontractor or collaborator.

[*Federally-supported is defined throughout the FWA and the Terms of Assurance as the U.S. Government providing any funding or other support.]

3. Compliance with the Federal Policy for the Protection of Human Subjects and Other Applicable Federal, State, Local, or Institutional Laws, Regulations, and Policies

When the Institution becomes engaged in federally-conducted or -supported human subjects research to which the FWA applies, the Institution and the institutional review boards (IRBs) designated under the Institution's Assurance will comply with the Federal Policy for the Protection of Human Subjects.

The reference in the Code of Federal Regulations is shown below for each department and agency which has adopted the Common Rule:

7 CFR part 1c

Department of Agriculture

10 CFR part 745

Department of Energy

http://www.hhs.gov/ohrp/humansubjects/assurance/filasurt.htm

| 14 CFR part1230 | National Aeronautics and Space Administration |
|-------------------------------------------|-----------------------------------------------|
| 15 CFR part 27 | Department of Commerce |
| 16 CFR part 1028 | Consumer Product Safety Commission |
| 22 CFR part 225 | Agency for International Development |
| 24 CFR part 60 | Department of Housing and Urban Development |
| 28 CFR part 46 | Department of Justice |
| 32 CFR part 219 | Department of Defense |
| 34 CFR part 97 | Department of Education |
| 38 CFR part 16 | Department of Veterans Affairs |
| 40 CFR part 26 | Environmental Protection Agency |
| 45 CFR part 46 | Department of Health and Human Services |
| 45 CFR part 46 (by Executive Order 12333) | Central Intelligence Agency |
| 45 CFR part 690 | National Science Foundation |
| 49 CFR part 11 | Department of Transportation |

For any federally-conducted or -supported human subjects research to which the FWA applies, the Institution also will comply with any additional human subjects regulations and policies of the department or agency which conducts or supports the research and any other applicable federal, state, local, or institutional laws, regulations, and policies. When the Institution is engaged in human subjects research conducted or supported by the Department of Health and Human Services (HHS), the Institution will comply with all subparts of the HHS regulations at Title 45 Code of Federal Regulations part 46 (45 CFR part 46, subparts A, B, C, and D).

Human subjects research conducted or supported by each federal department or agency listed above will be governed by the regulations as implemented by the respective department or agency. The head of the department or agency retains final judgment as to whether a particular activity conducted or supported by the respective department or agency is covered by the Common Rule. If the Institution needs guidance regarding implementation of the Common Rule and other applicable federal regulations, the Institution should contact appropriate officials at the department or agency conducting or supporting the research. For federally-conducted or –supported research covered by the FWA, the department or agency that conducts or supports the research retains final authority for determining whether the Institution complies with the Terms of Assurance. If HHS receives an allegation or indication of noncompliance related to human subjects research that is covered by the FWA and is conducted or supported solely by a Common Rule department or agency other than HHS, HHS will refer the matter to the other department or agency for review and action as appropriate.

Please note that if the Institution voluntarily extends the Common Rule or the Common Rule and

subparts B, C, and D of the HHS regulations at 45 CFR part 46 to all research regardless of support, OHRP will have the authority to ensure that the Institution complies with this commitment for all research to which the FWA applies that is not federally-conducted or –supported.

4. Written Procedures*

- a) The Institution submitting the FWA has written procedures* for ensuring prompt reporting to the IRB, appropriate institutional officials, the head of any department or agency conducting or supporting the research (or designee), any applicable regulatory body, and OHRP of any:
 - 1. unanticipated problems involving risks to subjects or others;
 - 2. serious or continuing noncompliance with the federal regulations or the requirements or determinations of the IRB(s); and
 - 3. suspension or termination of IRB approval.

Upon request, the Institution will provide a copy of these written procedures to OHRP and any department or agency conducting or supporting research covered by the FWA.

- b) The Institution must ensure that the IRB(s) designated under the FWA has established written procedures* for:
 - 1. conducting IRB initial and continuing review (not less than once per year) of research, and reporting IRB findings to the investigator and the Institution;
 - 2. determining which projects require review more often than annually and which projects need verification from sources other than the investigator that no material changes have occurred since the previous IRB review; and
 - 3. ensuring prompt reporting to the IRB of proposed changes in a research activity and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval, except when necessary to eliminate apparent immediate hazards to the subjects.

Upon request, the Institution will provide a copy of these written procedures to OHRP and any department or agency conducting or supporting research covered by the FWA.

[*For HHS-conducted or -supported human subjects research, see OHRP guidance on written IRB procedures on the OHRP website at http://www.hhs.gov/ohrp/humansubjects/guidance/irbgd107.htm.]

5. Scope of IRB(s)'s Responsibilities

All human subjects research to which the FWA applies, except for research exempted or waived in accordance with Sections 101(b) or 101(i) of the Common Rule, will be reviewed, prospectively approved, and subject to continuing review at least annually by the designated IRB(s). The IRB(s) will have authority to approve, require modifications in, or disapprove the covered human subjects research. For research approved by the IRB(s), further appropriate review and approval by any department or agency conducting or supporting the research or by officials of the institution holding the FWA may be required.

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Terms of the Federalwide Assurance

6. Informed Consent Requirements

Except for research exempted or waived in accordance with Sections 101(b) or 101(i) of the Common Rule, informed consent for research to which the FWA applies will be:

- a) sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by, Section 116 of the Common Rule; and
- b) appropriately documented, in accordance with, and to the extent required by, Section 117 of the Common Rule.

7. Requirement for Assurances for Collaborating Institutions

When the Institution holding the FWA is either a) the primary awardee under a federal grant, contract, or cooperative agreement supporting research to which the FWA applies, or b) the coordinating center for federally-conducted or –supported research to which the FWA applies, the Institution is responsible for ensuring that all collaborating institutions engaged in such research operate under an appropriate OHRP-approved or other federally-approved assurance for the protection of human subjects.

An institution holding an FWA may collaborate with another institution that does not have an FWA. In such circumstances, a collaborating institution may operate under the FWA with the approval of the department or agency conducting or supporting the research and the institution holding the FWA.

For federally-conducted or –supported research covered by the FWA, the department or agency that conducts or supports the research retains final authority for determining which institutions are engaged in the research and need to hold an assurance for the protection of human subjects.

8. Written Agreements with Independent Investigators Who are not Otherwise Affiliated with the Institution

When the Institution holding the FWA is either a) the primary awardee under a federal grant, contract, or cooperative agreement supporting research to which the FWA applies, or b) the coordinating center for federally-conducted or –supported research to which the FWA applies, the Institution is responsible for ensuring that all collaborating independent investigators engaged in such research operate under an appropriate OHRP-approved or other federally-approved assurance for the protection of human subjects.

The engagement in federally-conducted or –supported human subjects research activities to which the FWA applies by each independent investigator who is not otherwise an employee or agent of the Institution may be covered under the FWA only in accordance with a formal, written agreement of commitment to relevant human subject protection policies and IRB review. OHRP's sample Individual Investigator Agreement (see http://www.hhs.gov/ohrp/humansubjects/assurance/unaflsup.rtf) may be used or adapted for this purpose, or the Institution may develop its own commitment agreement in coordination with the department or agency conducting or supporting the research. Institutions must maintain commitment agreements on file and provide copies upon request to OHRP and any department or agency conducting or supporting the research.

For federally-conducted or –supported research covered by the FWA, the department or agency that conducts or supports the research retains final authority for determining which independent

investigators are engaged in the research and need to be covered by a written commitment agreement with the institution holding the FWA.

9. Institutional Support for the IRB(s)

The Institution will ensure that each IRB designated under the FWA has meeting space and sufficient staff to support the IRB's review and recordkeeping duties.

10. Compliance with the Terms of Assurance

The Institution accepts and will follow items 1-9 above and is responsible for ensuring that (a) the IRB(s) designated under the FWA agree to comply with these terms; and (b) the IRB(s) possess appropriate knowledge of the local research context for all research to which the FWA applies (please refer to the OHRP Guidance on IRB Knowledge of Local Research Context on the OHRP website at http://www.hhs.gov/ohrp/humansubjects/guidance/local.htm).

Any designation under the FWA of the IRB of another institution or organization must be documented by a written agreement between the Institution holding the FWA and the IRB organization outlining their relationship and include a commitment that the designated IRB will adhere to the requirements of the FWA. OHRP's sample IRB Authorization Agreement may be used for such purpose, or the parties involved may develop their own agreement. This agreement should be kept on file at both institutions/organizations and made available upon request to OHRP and any department or agency conducting or supporting research covered by the FWA.

11. Assurance Training

The OHRP Assurance Training Modules (see http://137.187.172.153/CBTs/Assurance/login.asp) describe the major responsibilities of the Institutional Signatory Official, the Human Protection Administrator (e.g., Human Subjects Administrator or Human Subjects Contact Person), and the IRB Chair(s) that must be fulfilled under the FWA. OHRP strongly recommends that the Institutional Signatory Official, the Human Protections Administrator, and the IRB Chair(s) personally complete the relevant OHRP Assurance Training Modules, or comparable training that includes the content of these modules, prior to submitting the FWA.

12. Educational Training

OHRP strongly recommends that the Institution and the designated IRB(s) establish educational training and oversight mechanisms (appropriate to the nature and volume of its research) to ensure that research investigators, IRB members and staff, and other appropriate personnel maintain continuing knowledge of, and comply with, the following: relevant ethical principles; relevant federal regulations; written IRB procedures; OHRP guidance; other applicable guidance, state and local laws; and institutional policies for the protection of human subjects. Furthermore, OHRP recommends that a) IRB members and staff complete relevant educational training before reviewing human subjects research; and b) research investigators complete appropriate institutional educational training before conducting human subjects research.

13. Renewal of Assurance

All information provided under the FWA must be renewed or updated at least every 36 months (3 years), even if no changes have occurred, in order to maintain an active FWA. Failure to update this

information may result in restriction, suspension, or termination of the Institution's FWA for the protection of human subjects.

DOMESTIC INSTITUTIONS ACCEPTING THESE TERMS MAY PROCEED WITH THE ASSURANCE FILING PROCESS

[Return to OHRP Assurance Main Page]

B. TERMS OF THE FEDERALWIDE ASSURANCE (FWA) FOR INTERNATIONAL (NON-U.S.) INSTITUTIONS

1. Human Subjects Research Must Be Guided by Ethical Principles

All of the Institution's human subjects research activities, regardless of whether the research is subject to U.S. federal regulations, will be guided by one of the following statements of ethical principles: (a) The World Medical Association's Declaration of Helsinki (as adopted in 1996 or 2000); (b) The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research of the U.S. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research; or (c) other appropriate international ethical standards recognized by U.S. federal departments and agencies that have adopted the U.S. Federal Policy for the Protection of Human Subjects, known as the Common Rule.

2. Applicability

These terms apply whenever the Institution becomes engaged in human subjects research conducted or supported* by any U.S. department or agency that has adopted the Common Rule, unless the research is otherwise exempt from the requirements of the Common Rule or a U.S. federal department or agency conducting or supporting the research determines that the research shall be conducted under a separate assurance. In general, the Institution becomes so engaged whenever (a) the Institution's employees or agents intervene or interact with human subjects for purposes of U.S. federally-conducted or —supported research; (b) the Institution's employees or agents obtain individually identifiable private information about human subjects for purposes of U.S. federally-conducted or —supported research; or (c) the Institution receives a direct award to conduct U.S. federally-supported human subjects research, even where all activities involving human subjects are carried out by a subcontractor or collaborator.

If a U.S. federal department or agency head determines that the procedures prescribed by the institution afford protections that are at least equivalent to those provided by the U.S. Federal Policy for the Protection of Human Subjects, the department or agency head may approve the substitution of the foreign procedures in lieu of the procedural requirements provided above, consistent with the requirements of section 101(h) of the U.S. Federal Policy for the Protection of Human Subjects.

[*Federally-supported is defined throughout the Assurance document and the Terms of Assurance as the U.S. Government providing any funding or other support.]

3. Compliance with Laws, Regulations, Policies, and Guidelines

When the Institution becomes engaged in U.S. federally-conducted or –supported human subjects research to which the FWA applies, the Institution and institutional review boards (IRBs) designated under the FWA at a minimum will comply with one or more of the following:

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http://www.hhs.gov/ohrp/humansubjects/assurance/filasurt.htm

- a) The U.S. Federal Policy for the Protection of Human Subjects (see section 3 of the Terms of the FWA for Institutions within the United States for a list of U.S. federal departments and agencies that have adopted the Common Rule);
- b) The Common Rule and subparts B, C, and D of the U.S. Department of Health and Human Services (HHS) regulations at 45 CFR part 46;
- c) The U.S. Food and Drug Administration (FDA) regulations at 21 CFR parts 50 and 56;
- d) The May 1, 1996, International Conference on Harmonization E-6 Guidelines for Good Clinical Practice (ICH-GCP-E6), Sections 1 through 4;
- e) The 2002 Council for International Organizations of Medical Sciences (CIOMS) International Ethical Guidelines for Biomedical Research Involving Human Subjects;
- f) The 1998 (with 2000, 2002, 2005 amendments) Medical Research Council of Canada Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans;
- g) The 2006 Indian Council of Medical Research Ethical Guidelines for Biomedical Research on Human Subjects; or
- h) Other standard(s) for the protection of human subjects recognized by U.S. federal departments and agencies which have adopted the U.S. Federal Policy for the Protection of Human Subjects.

All U.S. federally-conducted or -supported human subjects research to which the FWA applies will also comply with any additional human subjects regulations and policies of the U.S. federal department or agency which conducts or supports the research and any other applicable U.S. federal, international, state, local, or institutional laws, regulations, and policies.

The head of the U.S. federal department or agency retains final judgment as to whether a particular activity conducted or supported by the respective department or agency is covered by the Common Rule. If the Institution needs guidance regarding implementation of the Common Rule and/or other applicable U.S. federal regulations, the Institution should contact appropriate officials at the U.S. federal department or agency conducting or supporting the research. For U.S. federally-conducted or supported research covered by the FWA, the U.S. federal department or agency that conducts or supports the research retains final authority for determining whether the Institution complies with the Terms of Assurance. If HHS receives an allegation or indication of noncompliance related to human subjects research that is covered by the FWA and is conducted or supported solely by a Common Rule department or agency other than HHS, HHS will refer the matter to the other U.S. federal department or agency for review and action as appropriate.

4. IRB Written Procedures*

- a) The Institution submitting the FWA has established written procedures* for ensuring prompt reporting to the IRB, appropriate institutional officials, the head of any U.S. federal department or agency conducting or supporting the research (or designee), any applicable regulatory body, and OHRP of any:
 - 1. unanticipated problems involving risks to subjects or others;

- 2. serious or continuing noncompliance with the applicable U.S. federal regulations or the requirements or determinations of the IRB(s); and
- 3. suspension or termination of IRB approval.

Upon request, the Institution will provide a copy of these written procedures to OHRP and any department or agency conducting or supporting research covered by the FWA.

- b) The Institution must ensure that the IRB(s) designated under the FWA has established written procedures* for:
 - 1. conducting IRB initial and continuing review (not less than once per year), of research, and reporting IRB findings to the investigator and the Institution;
 - 2. determining which projects require review more often than annually and which projects need verification from sources other than the investigator that no material changes have occurred since the previous IRB review; and
 - 3. ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval, except when necessary to eliminate apparent immediate hazards to the subjects.

Upon request, the Institution will provide a copy of these written procedures to OHRP and any department or agency conducting or supporting research covered by the FWA.

[*For HHS-conducted or -supported human subjects research, see OHRP guidance on written IRB procedures on the OHRP website at http://www.hhs.gov/ohrp/humansubjects/guidance/irbgd107.htm.

5. Scope of IRB(s)'s Responsibilities

All U.S. federally-conducted or -supported research to which the FWA applies, except for research exempted or waived in accordance with sections 101(b) or 101(i) of the U.S. Common Rule, will be reviewed, prospectively approved, and subject to continuing review at least annually by the designated IRB(s). The IRB(s) shall have authority to approve, require modifications in, or disapprove the covered human subjects research. For research approved by the IRB(s), further appropriate review and approval by any U.S. federal department or agency conducting or supporting the research or by officials of the institution holding the FWA may be required.

6. Informed Consent Requirements

Except for research exempted or waived in accordance with Sections 101(b) or 101(i) of the U.S. Common Rule, informed consent for research to which the FWA applies will be:

- a) sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by, Section 116 of the U.S. Common Rule; and
- b) appropriately documented, in accordance with, and to the extent required by, Section 117 of the U.S. Common Rule.

7. Considerations for Special Class of Subjects

For HHS-conducted or supported human subjects research, the Institution will comply with the HHS regulations at 45 CFR part 46, subparts B, C, and D, prior to the involvement of pregnant women, fetuses, or neonates; prisoners; or children, respectively. For non-HHS U.S. federally-supported human subjects research, the Institution will comply with any human subject regulations and/or policies of the supporting U.S. federal department or agency for these classes of subjects.

8. Requirement for Assurances for Collaborating Institutions

When the Institution holding the FWA is either a) the primary awardee under a U.S. federal grant, contract, or cooperative agreement supporting research to which the FWA applies, or b) the coordinating center for U.S. federally-conducted or –supported research to which the FWA applies, the Institution is responsible for ensuring that all collaborating institutions engaged in such research operate under an appropriate OHRP-approved or other U.S. federally-approved assurance for the protection of human subjects.

An institution holding an FWA may collaborate with another institution that does not have an FWA. In such circumstances, a collaborating institution may operate under the FWA with the approval of the U.S. federal department or agency conducting or supporting the research and the institution holding the FWA.

For U.S. federally-conducted or –supported research covered by the FWA, the U.S. federal department or agency that conducts or supports the research retains final authority for determining which institutions are engaged in the research and need to hold an assurance for the protection of human subjects.

9. Written Agreements with Independent Investigators Who are not Otherwise Affiliated with the Institution

When the Institution holding the FWA is either a) the primary awardee under a U.S. federal grant, contract, or cooperative agreement supporting research to which the FWA applies, or b) the coordinating center for U.S. federally-conducted or –supported research to which the FWA applies, the Institution is responsible for ensuring that all collaborating independent investigators engaged in such research operate under an appropriate OHRP-approved or other U.S. federally-approved assurance for the protection of human subjects.

The engagement in U.S. federally-conducted or –supported human subjects research activities to which the FWA applies by each independent investigator who is not otherwise an employee or agent of the Institution may be covered under the FWA only in accordance with a formal, written agreement of commitment to relevant human subject protection policies and IRB review. OHRP's sample Individual Investigator Agreement (see http://www.hhs.gov/ohrp/humansubjects/assurance/unaflsup.rtf) may be used or adapted for this purpose, or the Institution may develop its own commitment agreement in coordination with the U.S. federal department or agency conducting or supporting the research. Institutions should maintain commitment agreements on file and provide copies upon request to OHRP or any U.S. federal department or agency conducting or supporting the research.

For U.S. federally-conducted or –supported research covered by the FWA, the U.S. federal department or agency that conducts or supports the research retains final authority for determining which independent investigators are engaged in the research and need to be covered by a written

commitment agreement with the institution holding the FWA.

10. Institutional Support for the IRB(s)

The Institution will ensure that each IRB(s) designated under the FWA has meeting space and sufficient staff to support the IRB's review and recordkeeping duties.

11. Compliance with the Terms of Assurance

The Institution accepts and will follow items 1-10 above and is responsible for ensuring that (a) the IRB(s) designated under the FWA agree to comply with these terms, and (b) the IRB(s) possess appropriate knowledge of the local research context for all research to which the FWA applies (please refer to the OHRP Guidance on IRB Knowledge of Local Research Context on the OHRP website at http://www.hhs.gov/ohrp/humansubjects/guidance/local.htm).

Any designation under the FWA of the IRB or another institution or organization should be documented by a written agreement between the Institution holding the FWA and the IRB organization outlining their relationship and include a commitment that the designated IRB will adhere to the requirements of the FWA. OHRP's sample IRB Authorization Agreement may be used for such purpose, or the parties involved may develop their own agreement. This agreement should be kept on file at both institutions/organizations and made available upon request to OHRP and any U.S. federal department or agency conducting or supporting research covered by the FWA.

12. Assurance Training

The OHRP Assurance Training Modules (see http://i37.187.172.153/CBTs/Assurance/login.asp) describe the major responsibilities of the Institutional Signatory Official, the Human Protection Administrator (e.g., Human Subjects Administrator or Human Subjects Contact Person), and the IRB Chair(s) that must be fulfilled under the FWA. OHRP strongly recommends that the Institutional Signatory Official, the Human Protections Administrator, and the IRB Chair(s) personally complete the relevant OHRP Assurance Training Modules, or comparable training that includes the content of these Modules, prior to submitting the FWA.

13. Educational Training

OHRP strongly recommends that the Institution and the designated IRB(s) establish educational training and oversight mechanisms (appropriate to the nature and volume of its research) to ensure that research investigators, IRB members and staff, and other appropriate personnel maintain continuing knowledge of, and comply with the following: relevant ethical principles; relevant U.S. regulations; written IRB procedures; OHRP guidance; other applicable guidance; national, state and local laws; and institutional policies for the protection of human subjects. Furthermore, OHRP recommends that a) IRB members and staff complete relevant educational training before reviewing human subjects research; and b) research investigators complete appropriate institutional educational training before conducting human subjects research.

14. Renewal of Assurance

All information provided under the FWA should be renewed or updated every 36 months (3 years), even if no changes have occurred, in order to maintain an active FWA. Failure to update this information may result in restriction, suspension, or termination of the Institution's FWA for the

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Terms of the Federalwide Assurance

http://www.hhs.gov/ohrp/humansubjects/assurance/filasurt.htm

protection of human subjects.

INTERNATIONAL INSTITUTIONS ACCEPTING THESE TERMS MAY PROCEED WITH THE ASSURANCE FILING PROCESS

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If you have questions about human subjects research, click ohrp@hhs.gov
If you have questions/suggestions about this web page, click Webmaster
Updated [07/09/2009]

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| Institutional Assurance | |
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PURPOSE

1. The purpose of this policy and procedure is to describe the process of managing the Federal Wide Assurance for UTHSC-H.

SCOPE

- 2. This policy and procedure is applicable to all UTHSC-H faculty, staff, and students, which include its schools, departments, divisions, and facilities.
- 3. This policy and procedure is also applicable to any research for which an Assurance or other agreement identifies UTHSC-H CPHS as the IRB of record.

POLICY

- 4. The UTHSC-H and the Department of Health & Human Services (DHHS) have signed a Federal Wide Assurance (FWA #00000667) that defines the obligation of the UTHSC-H to ensure the rights and welfare of human subjects of research are protected. Under the FWA, CPHS must review all proposed research involving human subjects to determine if adequate measures are in place to protect participants.
- 5. The UTHSC-H is committed to upholding its Assurance. The UTHSC-H delegates responsibility for insuring the rights, safety and welfare of human participants in research to the Executive Vice-President for Research (EVPR). It is the EVPR's responsibility to exercise appropriate administrative oversight to assure that UTHSC-H's policies and procedures for protecting the rights and welfare of human participants are applied in compliance with its Assurance.
- 5.1. All UTHSC-H human subjects research activities, regardless of whether the research is subject to federal regulations, will be guided by the ethical principles outlined in the Belmont Report which are respect for persons, beneficence, and justice.
- 5.2. UTHSC-H human subjects research activities will comply with other appropriate regulations and ethical standards such as the Common Rule, other Department of Health and Human Services regulations (45 CFR 46, 21 CFR 50, 56, 312, 812), Health Information Portability and Privacy Act and the ICH Guidelines.

PROCEDURE

6. The EVPR or designee will update the Assurance at least every 36 months, even if no changes have occurred, in order to maintain an active assurance approved by Office of Human Research Protections (OHRP).

- 7. The EVPR or designee will update the IRB Registration with OHRP at least every 36 months even if no changes have occurred. The IRB Roster will contain a list of members identified by name; earned degrees; representative capacity indications of experience such as board certifications, licenses, etc.
- 8. The EVPR or his/her designee will promptly report amendments to the Assurance or IRB Roster to OHRP via their electronic system.
- 9. The ORSC Director will maintain a copy of the Assurance within the ORSC office.

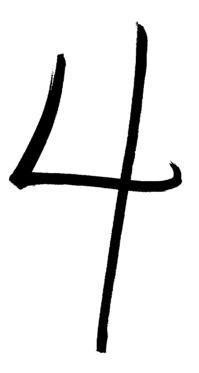
RESPONSIBILITY

10. The EVPR is responsible for maintaining an active assurance with the OHRP. The EVPR may delegate this responsibility to the ORSC Director.

Applicable Regulations and Guidelines
45CFR 46 (http://www.access.gpo.gov/nara/cfr/waisidx 04/45cfr46 04.html)

Return to Policies and Procedures Home Page

Updated 2/2009, Report broken links



| (s): Ph.D. | Assistant Professor | Tenured: Yes No X_ N/A | | >. | | Teaching Awards | | | | | | | |
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ANNUAL FACULTY REVIEW

Academic Year 2003-04

If you listed teaching activities above you MUST answer the questions noted below:

Extent to which these goals were achieved? (0 – 100%) $\,100\%$

What were your teaching goals for the last year?

1. To continue private tutorials for graduate and post-graduate students

2. To continue to assist in the preparation of K-23 grants and to participate as a consultant

Mentoring
Sylvia Frazier-Bowers – K23 recipient – collaborator on R01 grant submission
Sylvia Frazier-Bowers – K23 applicant – participated in resubmission, <u>appears application will be funded,</u> role on grant is statistical consultant
Joshua Samuels – K23 applicant – participated in resubmission, <u>appears application will be funded,</u> role on grant is statistical consultant

ANNUAL FACULTY REVIEW

Andrew Shaw - K23 applicant - participated in resubmission, role on grant is statistical consultant, paper preparation Academic Year 2003-04

David Eagleman - Asst Professor, Dept of Neurobiology - participated in development of study design, preparation of CPHS applications, design and set-up of study operations Anthony Estrera - K23 applicant - participated in developing study design and preparation of application, role on grant is statistical consultant

Graduate Student Committees

Carol Ann Linsner - Master's Committee (Susan Peterson) - graduated Yuhua Qi - Master's Committee (Dianna Milewicz) • graduated

Colleen Beuchner - Master's Committee (Michael Gambello) - ad hoc member - graduated Alice Schindler - Master's Committee (Steve Daiger) - ad hoc member - graduated

Lisa Vincent - Doctoral Committee (Dianna Milewicz)

Cynthia Trotter - Master's Committee (Bartlett Moore)

Jennifer Lemoine - Master's Committee (Jaou-Chen Huang) Tamara Soloman - Master's Committee (Jacqui Hecht)

Suma Shankar - Doctoral Committee (Steve Daiger) - ad hoc member

Graduate Students/Post-doctoral Fellows

Emily Gutter - assisted with statistical analysis

Catherine Ward - assisted with statistical analysis Hariya Pannu - assisted with statistical analysis

What are your teaching goals for next year?

To continue private tutorials for graduate and post-graduate students

Other Comments:

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ANNUAL FACULTY REVIEW

Academic Year 2003-04

SCHOLARLY ACTIVITIES

| RESEARCH GRANTS | % Effort | Total Grant Period | Total Award Amount |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|--------------------------|--------------------------|
| 1. Active research grants as P.I. Source(s): | | | |
| 2. Active research grants as Co-Investigator Source(s): NCRR. Buja, Pl NIAID, Okhuysen, Pl | 20% 5% | 2001-2006 2003-2008 | |
| 3. Pending grants as P.1. Source(s): NICHD, Fletcher, PI (King, co-PI, Core C) | 25% | | |
| 4. Pending grants as Co-Investigator Sources(s): NIH, Moeller, PI (R01) – submitted 6/04 NIH, Estrera, PI (K23) – submitted 6/04 NIH, Hecht, PI (R01) – submitted 2/04 NIH, Xia, PI (R01) – submitted 2/04 NIH, Samuels, PI (K23) – submitted 2/04 NIH, Shaw, PI (K23) – submitted 2/04 NIH, Shaw, PI (K03) – submitted 1/04 NIH, Frazier-Bowers (R21) – submitted 10/03 NIH, Gilstrap (U10) – submitted 10/03 | 5-10% 5% 5% 5% 5% 5% 10% | | |
| 5. Active research grants as sponsor, etc. | | | |
| 6. Pending research grants as sponsor, etc. | | | |

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| PUBLICATIONS AND PRESENTATIONS | Number Of |
|---------------------------------------------------------|--------------|
| 7. Books/Book Chapters | 0 |
| 8. Articles published/accepted for publication | 3 |
| 9. Presentations at scientific meetings | 0 |
| 10. Invited presentations (local/Houston area) | |
| 11. Invited presentations (National) | 2 |
| 12. Invited presentations (International) | 0 |
| 13. Committees of scientific organizations | 0 |
| 14. Editorial board member | 0 |
| 15. Study section member | - |
| 16. Advisory board member | 0 |
| 17. Offices held in medical or scientific organizations | 0 |
| 18. Patents | 0 |
| 19. Other (specify): | |
| | _ |

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ANNUAL FACULTY REVIEW

Academic Year 2003-04

If you listed research activities above you MUST answer the questions noted below:

What were your research goals for the last year?

My stated goal was to submit 3 grant proposals and to initiated independent research project

Extent to which these goals were achieved? (0 – 100%) 100% During the last year, I participated in the submission of 9 grant applications (I-P01, I-U10, 3-R01, 3-K23, I-R21).

To address the goal of independent research project, as a part of the P01 (Fletcher) I developed and am currently executing novel research investigating the relationship between genetic polymorphisms in the folate and glucose pathway and subsequent development of learning disabilities and other neuropsychiatric sequela in children with spina bifida. This was a novel, cross-project addition to the P01 and was highlighted by the reviewers as a significant scientific contribution.

What are your research goals for next year?

My goal is to reduce the number of grant collaboration and to initiate a research project in the area of cardiovascular metabolism.

Other Comments:

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ANNUAL FACULTY REVIEW

Academic Year 2003-04

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| CLINICAL ACTIVITIES: For any clinical activities listed you MUST answer the questions noted below. |
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| | :linical laboratory): |
|-----------------------------------------------|----------------------------------------------------------------------------------------|
| Main sites: | in other clinical activities (please specify, eg., supervising a clinical laboratory): |
| Number of hours spent in direct patient care: | Number of hours spent in other clinical activities (p |

What were your clinical goals for the last year?

To what extent were these goals achieved? (0-100%)

What are your clinical activities/goals for next year?

In January, I will initiate training in the Medical Genetics Fellowship program leading to my certification as a Ph.D, Medical Geneticist. The only activities that are outstanding on this certification are clinical hours and a counseling course.

Other Comments:

ANNUAL FACULTY REVIEW

Academic Year 2003-04

ADMINISTRATIVE/OTHER ACTIVITIES

| | Member | Chair | Dates of Service |
|----------------------------------------------|--------|-------|------------------|
| Departmental Committees: | | | |
| | | | |
| | | | |
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| | | | |
| | Member | Chair | Dates of Service |
| Medical School, Hospital and HSC Committees: | × | | 2001-present |
| GCRC Scientific Advisory Board | × | | 2002-present |
| GSEC Committee | | | |
| | | | |

Other Activities (i.e., mentoring of junior faculty members). Briefly describe the nature of the activity. Mentoring of junior faculty/ post-doctoral fellows/graduate students - these activities are described under

Development of LIMS system - Project management, data management, design, supervisory activities, training, teaching activies deployment

If you listed administrative activities above you MUST answer the questions noted below:

What were your administrative goals for the last year?

- 1. To continue to develop mentoring and teaching relationship across UTH
 - 2. To continue the development of the Nautilus LIMS system.

Extent to which these goals were achieved? (0 – 100%) 100%

As detailed in the teaching section, I have increased the number of students that I am mentoring on a regular basis. Additionally, I am beginning to mentor junior faculty (Dr. Eagleman) who are initiating genetic research protocols.

The Nautilus LIMS system was deployed in FY2003-2004 in the Division of Medical Genetics. The system overview was presented to the Division of Rheumatology and the GCRC in Summer 2004. This system is featured in the GCRC renewal application.

What are your administrative goals for next year?

Course/Program Director:

Teaching Activity:

Note:

Academic Year 2003-04

ANNUAL FACULTY REVIEW

Academic Year 2003-04

My administrative goal for FY 2004-2005 is to continue developing mentoring and teaching relationships across UTH and to significantly reduce the amount of time on non-research activities such as the LIMS system.

Other Comments:

| TEACHING EVALUATIONS BY COURSE/PROGRAM DIRECTOR(S): Facuity intember: |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| student/trainee evaluation of the faculty member's teaching effectiveness is an essential part of the Annual Faculty Review and faculty |
| evelopment. |
| The faculty member (or the department chair) should request that <u>each course/program director submit</u> to the department chair <u>a typed summary statement</u> of the faculty member's teaching strengths and weaknesses based on the student/trainee evaluations. |
| |
| Note: This form can be duplicated for sending to course/program directors |

ANNUAL FACULTY REVIEW

Academic Year 2003-04

Typed Summary Statement by Course/Program Director of the faculty member's teaching strengths and weaknesses:

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ANNUAL FACULTY REVIEW

INPUT BY DEPARTMENTAL PEER COMMITTEE: Academic Year 2003-04

Overall Level of Performance (a category MUST be checked):

Category 2* - Performance will benefit from institutional assistance: Category 1 - Satisfactory:

Category 3*- Unsatisfactory:

*Add appropriate comments and suggest remediation for a Category 2 or Category 3 assessment: (MUST BE TYPED)

Comments (optional):

(Attach additional sheet if necessary) EVALUATION BY DIVISION DIRECTOR (if applicable): (MUST BE TYPED)

on data analysis. In addition, her current career plans do not align with the goals of the Division of Medical Genetics, specifically her attendance at meetings, including Division meetings, UCRC meetings, and medical school committee meetings; (3) turn around time Dr. King needs improvement in the following area: (1) obtaining funding of independent and collaborative research projects; (2) plan to do a fellowship in Clinical Genetics in the Division of Pediatric Genetics.

EVALUATION BY THE DEPARTMENT CHAIR: (MUST BE TYPED)

Progress of last year's goals:

Mutually agreed goals for the next academic year:

Comments:

Date Department Chair Signature:

ç

ANNUAL FACULTY REVIEW

Academic Year 2003-04

| I have read the chairman's comments and choose/choose not to respond. I | understand that if I choose to respond, my written comments must be attached | to this document and the complete review packet will be forwarded to the Dean. |
|-------------------------------------------------------------------------|------------------------------------------------------------------------------|--------------------------------------------------------------------------------|

| Date |
|---------------------------|
| Signature: Faculty Member |

C

Page 1 of 1

Terri M. King

From: Hope Northrup [Hope.Northrup@uth.tmc.edu]

Sent: Wednesday, October 20, 2004 4:23 PM

Bruce.C.Kone@uth.tmc.edu To:

Dear Bruce,

I wanted to drop you a note about your faculty member Terri M. King, PhD, who has recently discussed with me her desire to undergo training for Board Eligibility in PhD Medical Genetics. As you are probably aware, I am the Director of the Training Programs in Medical Genetics at UT. We currently have training programs in MD Medical Genetics and PhD Medical Genetics. The PhD Medical Genetics Program is a 2-year program requiring 1 year of clinical work and 1 year of research as specified by the American Board of Medical Genetics (ABMG). Dr. King and I discussed that she could accomplish the program by devoting roughly half of her time to the clinical endeavors and half time performing research. Her research component will probably consist of our joint project on spina bifida (recently reviewed with priority score of 2.6% to begin funding sometime between December-March). Dr. King has 25% effort on the SB project. Dr. King has 20% funding on the CRC. Our plan is that the clinical and research work will run concurrently. I understand from Dr. King that you are supportive of her plans.

Board certification in PhD Medical Genetics has several advantages for Dr. King. Board certification in PhD Medical Genetics allows an individual who has a PhD to become a member of the American College of Medical Genetics (ACMG), our equivalent body to the American College of Physicians in Internal Medicine. The credentialing allows for service on high-profile national committees that would otherwise not be available. Locally, Dr. King has been serving on numerous committees of individuals in our Genetic Counseling Masters Program as well as working with our Medical Genetics Fellows on their research projects. Her experiences in undergoing the training will enhance her credentials as a teacher in these programs as well as help her in mentoring. Finally, Dr. Jacqui Hecht in the Pediatrics Department is a board-certified PhD Medical Geneticist. Dr. Hecht evaluates patients on a regular basis. Her clinical work has been key to her successful translational research program.

There is ample precedent for individuals to retain faculty positions while undergoing Medical Genetics training here as well as at other institutions. We currently have an MD Genetics part-time fellow who is a full-time faculty member at UTMB (Dr. Neena Champaigne). She and I have had discussions about logistics, time commitment, etc. She is interested in career enhancement and receiving the ABMG certification should be helpful to her in her career advancement as well as being a positive asset to our institution. It is my opinion that Dr. King is committed to obtaining the training that is required for certification. I am very supportive and feel that our program can help her achieve her goal. Please give me a call (ext 5761) or email for any further information and discussions.

Best. Hope

Hope Northrup, M.D. Director, Division of Medical Genetics Professor, Department of Pediatrics The University of Texas Medical School at Houston 6431 Fannin Street Houston, Texas 77030 Telephone: (713) 500-5760 FAX: (713) 500-5689

Faculty Review and Evaluation

Page 1 of 1

Terri M. King

From:

Terri M. King [terri.m.king@uth.tmc.edu]

Sent:

Monday, November 29, 2004 12:32 PM

To:

'Bruce Kone'

Subject:

Faculty Review and Evaluation

Signed By: terri.m.king@uth.tmc.edu

Importance: High

Thave just received a copy of my evaluation from Dianna including her comments. During my faculty review meeting with you and Dianna. I plan to ask that those comments be deleted and to provide documentation to support my assertion that they are without merit. I have prepared a written memo which responds to each comment in detail - I will bring this to the evaluation, but I can also provide you with a copy prior to our meeting.

I realize that this discussion can take longer than what is alloted for an evaluation and perhaps we should extend the time allowed for the evaluation. Alternatively, I would be happy to meet with you separately to go over my concerns.

Terri

Terri M. King, Ph.D. Department of Internal Medicine **Division of Medical Genetics** University of Texas - Houston Medical School 6431 Fannin, MSB 4.040 Houston, Texas 77030 Phone - 713-500-5659 Mobile - 832-724-7835 E-mail - Terri.M.King@uth.tmc.edu

To: Bruce C. Kone, M.D., FACP, FCP, FAHA, FASN Chairman, Department of Internal Medicine

Dianna Milewicz, M.D. Ph.D. Director, Division of Medical Genetics

From: Terri M. King, Ph.D.

Date: November 29, 2004

Re: Comments on Faculty Evaluation

I would like to request that the comments from Dr. Milewicz on my faculty evaluation be deleted. I believe that they are capricious and are not substantiated by fact. I have provided my rationale for this request below.

Dr. King needs improvement in the following areas: (1) obtaining funding of independent and collaborative research projects.

Over the past year, I have participated in the development and submission of nine NIH projects, of which three have fundable scores. I have more than doubled my funding level to 60%, whereas at this point last year it was at 25%. On my largest project (Fletcher, P01), I have the responsibility for several specific aims in addition to being the Co-P.I. on the Data Analysis Core (Core C). These efforts are likely to lead to independent funding, most likely through supplemental grants. Since this grant is schedule to begin early 2004, there simply hasn't been sufficient time to fully develop that research line. Additionally, I am developing a collaboration with Dr. Heinrich Taegtmeyer which on track to lead to submission of a supplemental grant within the next year.

Previous attempts to initiate independent research have been hampered by Dr. Milewicz when she promised a Fellow the opportunity to serve as PI on a grant for the specific aims that I had developed. This led to significant confusion on the part of the Fellow and myself as to whose research this project was. This process continued when Dr. Milewicz refused to permit me to have the approvals for research in my name. I ultimately abandoned this particular research project because (1) it was no longer clear that I would get appropriate credit for the research and (2) the data were to be collected under the TexGen structure (as directed by Dr. Milewicz) which would then hamper my ability to analyze the data independently, since TexGen would own the samples and would control access to them.

(2) attendance at meetings, including Division meetings, UCRC meetings and medical school committee meetings

<u>Division meetings</u> – prior to this evaluation, the meetings that Dr. Milewicz is calling Division meeting have been referred to as Milewicz laboratory meetings. The stated purpose of those meetings by Dr. Milewicz is to update her on what her research laboratory is doing. There are no Divisional issues discussed and only Dr. Milewicz sets the agenda. At this point, I have no active projects with the Milewicz laboratory and thus I have not felt it necessary to attend the meetings. This is consistent with other groups that I work with that have internal laboratory meetings. I am always available to attend should there be a reason and I can provide a contribution.

<u>UCRC meetings</u> – I currently serve on the SAC committee and I regularly attend these meetings. I am often asked to review protocols for the meeting and I present them in person. I have also attended UCRC staff meetings, site visit preparations, retreats and other scheduled meetings. In the past, Dr. Milewicz has expected me to attend the Director's meeting. However, since I am not the director or co-director of the UCRC DNA Core Laboratory, I discussed my attendance with Dr. Okhuysen. He is in agreement with me that it is not necessary for me to attend the Director's meeting.

Medical school committee meetings – I currently serve on the GSEC committee and am in my second year. My first year of service was without incident and I participated in meetings, retreats for evaluation of research prizes and e-mail discussions about the operation of the committee. In September of this year, Dr. Waxman assumed the Chair and the meeting times were changed. I inadvertently missed the September meeting. On the day of the October meeting, I left work early for illness. The November meeting was cancelled by Dr. Waxman. Shortly after the October meeting, Dr. Waxman contacted Norma Adams (the executive assistant in the division) asking if I was planning to continue on the committee. Dr. Waxman did not contact me directly about his concerns about these two meeting. The absences were coincidental and, in only one case, was unexcused.

I do not believe that these incidents reflect a pattern of negligence when it comes to my committee and meeting obligations.

(3) turn around time on data analysis

In a previous meeting with Dr. Milewicz on May 7th, 2004, she indicated that she was concerned about turn around time for data analysis. In that meeting, she brought forth 2 incidents where she did not feel that turn around was not timely. In both of those incidents, data had not been given to me to be analyzed. There is an additional documented incident where I was reprimanded for slow data analysis, but the data had not been delivered to me.

To my knowledge, Dr. Milewicz has not contacted anyone else that I have performed data analysis for to fully evaluate my turn around time. I feel strongly that this comment is based on these three incidents which are not attributable to performance issues on my behalf.

My time management skills are well developed and are reflected in the large number of projects I manage with multiple collaborators.

In addition, her current career plans do not align with the goals of the Division of Medical Genetics, specifically her plan to do a fellowship in Clinical Genetics in the Division of Pediatric Genetics [sic].

In the Faculty Education Development section of the HOOP, the University policy is "The University of Texas Health Science Center at Houston (UTHSC-H) encourages its faculty to continue their educational development by participating in job-oriented educational activities, including taking courses and/or attaining additional degrees that will assist or complement faculty members' individual goals and enhance their role in serving the mission of the university."

There are several reasons that I want to pursue certification in Clinical Genetics.

- As a PhD in a clinical department, I am at a competitive disadvantage for promotion and tenure decisions, as well as departmental support and resources. By adding a clinical component to my skill set, I feel strongly that my position within the Department and my career development will be enhanced.
- 2. Being Board-certified will permit me to join the American College of Medical Genetics and will make me eligible for national committee service. Both of these eligibilities are distinct career enhancements.
- 3. Participating in clinical operations will permit me to have direct contact with patients and will enhance my research efforts. At this point, my only access to patients for research is through collaboration.

- While I have been successful in establishing collaborations, the opportunity to have truly independent research is a distinct career advantage.
- 4. The Medical School currently does not have a Medical Geneticist dedicated to the evaluation and risk assessment of general adult-onset genetic conditions, such as neurological syndromes (e.g. Huntington Disease) or cancer. This is a niche which I would be ideal to fill within my position in Internal Medicine and with my previous experience with cancer and neurological research and risk assessment.

In the Academic Freedom and Responsibility section of the HOOP, the University policy is "The fundamental responsibilities of a faculty member as a teacher and scholar include the maintenance and demonstration of competence in his or her field of specialization." Pursuing this certification meets the criteria of maintaining competence in my field of specialization, which is statistical genetics and genetic epidemiology. Over the past several years, Dr. Milewicz has actively impeded my ability to maintain my standing in the field of genetic research by assigning tasks to me that are not in my area of expertise or interest. The primary task that Dr. Milewicz has assigned to me is the development of databases to support her research interests. While I have more than a casual familiarity with database design, including design of laboratory information management systems, these projects have not contributed to my growth as a researcher and academician. These are efforts which are not scholarly and will result in no publications. The time necessary for these projects have detrimentally affected my efforts to initiate independent research. Dr. Milewicz has not provided an alternative other than to continue to manage her databases, which is counter to academic career development. She additionally has not provided how this plan is counter to the goals of the Division.

Finally, Dr. Milewicz has been quite vocal in her displeasure regarding my independent collaborations with other groups, notably the Medical Genetics group in Pediatrics. I believe that this displeasure is a result of disagreements between Dr. Milewicz and Dr. Northrup which occurred many years prior to my arrival at UT Houston. I am not, nor have I been, a participant in these disagreements. I feel that this political situation is the primary reason behind Dr. Milewicz' lack of support of my plan to become Board Certified, rather than the unstated goals of the Division of Medical Genetics.

Mobile - 832-724-7835

E-mail - Terri.M.King@uth.tmc.edu

Terri M. King

From: Sent: Terri M. King [terri.m.king@uth.tmc.edu] Tuesday, November 30, 2004 2:34 PM

To:

Pablo.C.Okhuysen@uth.tmc.edu

Subject: Signed By: GCRC Director's Meetings terri.m.king@uth.tmc.edu

Importance:

High

Pablo

I am sorry to bother you on your vacation.

I had my evaluation today with Dianna and Dr. Kone. During the course of the evaluation, Dianna stated that I never attended the Director's meeting on Thursday morning despite your explicit instruction that my attendance was required. She indicated that you were quite upset that I was not attending and that you had spoken to her on numerous occassions requesting ther assistance in ensuring my attendance.

It was my understanding that, while I was welcome to attend the meetings, that my attendance was not required: Please correct me if I am wrong. I sincerely believed that the Director's meetings were for the administrative structure of the UCRC and, that since I was not part of the administration, I was not required to attend.

My attendance at the GCRC meetings was a part of a fairly negative review—so if you could clarify my attendance requirement, I would be most appreciative. If you prefer, you can respond directly to Dr. Kone.

I truly enjoy participating in the GCRC and I hope that my participation has been a positive for the GCRC.

Thanks in advance:

Terru

Terri M. King, Ph.D.
Department of Internal Medicine
Division of Medical Genetics
University of Texas - Houston Medical School
6431 Fannin, MSB 4.040
Houston, Texas 77030
Phone - 713-500-5659
Mobile - 832-724-7835
E-mail - Terri.M.King@uth.tmc.edu

Terri M. King

From:

Terri M. King [terri.m.king@uth.tmc.edu] Tuesday, November 30, 2004 3:47 PM

:ent

'Bruce Kone'

To: Subject: Signed By:

Follow-up on Evaluation terri.m.king@uth.tmc.edu

Bruce -

Thank you for your thoughts today in my departmental evaluation. I wanted to update you on a couple of issues

I have contacted Pablo Okhuysen directly to request clarification on my participation in the GCRC Director's meetings - I have checked the e-mail distribution list, agenda and roster for this meeting and my name has not and does not appear as a participant in this meeting. My understanding was that I was welcome to attend, but that the meeting was designed for and required of the administrative structure of the GCRC

I would also like to request that you solicit evaluations from collaborators who can provide a balanced picture of my activities as a collaborator and contributing scientist. These investigators can comment on my scholarship, timeliness with regards to analysis and attention to study operations details (e.g. participation in meetings, etc). While I will agree that my contributions to these projects does not meet the standard of independent research. I do have significant scholarly contributions which will lead to independent research avenues

The following are some collaborators with whom I have a significant relationship and can comment on performance issues. If you need additional references, please let me know.

- Hope Northrup
- Jack Fletcher
- Jacqui Hecht
- Steve Daiger
- Sylvia Frazier-Bowers
- Heinrich Taegtmeyer (this is a new collaboration, but one that is likely to result in independent research projects)

One point that I would like to make is that one issue that impeded development of independent research is independent access to patients. I don't have a clinical population on which to develop hypotheses or to recruit patients. Inherent in the strategy to develop collaborative grants with specific aims that I designed is to obtain access to patient populations. The two major projects which I am using to initiate independent research are Dr. Fletcher's P01 and Dr. Taegtmeyer's R01 with the enthusiastic support of both PI and the explicit goal to generate supplemental grants

I would also like to re-emphasize that focusing on collaborative research projects was driven by the need to cover my salary Dr. Arnett and Dr. Milewicz were insistent that I cover my salary as quickly as possible and that I should do as many grants as possible. It simply was an ecomony of scale to participate in as many grants as possible, even though it was at the cost of initiating independent research. Given my position as a statistician, it certainly was indicated that this was an appropriate strategy for promotion and tenure (as modelled by Dr. Ahn). After conversations with you, and a more complete understanding of the promotion/tenure process. Lagree that getting independent research project initiated is a high priority. However, please recognize that this is a distinct change in the expectations placed on me

Terri

Terri M. King, Ph.D. Department of Internal Medicine **Division of Medical Genetics University of Texas - Houston Medical School** 6431 Fannin, MSB 4.040 Houston, Texas 77030 Phone - 713-500-5659



http://us.mg3.mail.yahoo.com/dc/launch?.gx=1&.rand=ae7ts791...

Print

From: King, Terri M (Terri.M.King@uth.tmc.edu)

To: tking_tx@yahoo.com;

Date: Mon, November 2, 2009 9:46:55 AM

Cc:

Subject: FW: pediatrics

tking

----Original Message----

From: Bruce C Kone [mailto: Bruce C.Kone@uth.tmc.edu]

Sent: Tuesday, August 30, 2005 10:40 AM

To: King, Terri M Subject: pediatrics

Terri,

I've talked with Dr. Colasurda about your situation, and after discussion with Hope Northrup and Jack Fletcher, the Dept. of Pediatrics has agreed to take you as a full-time faculty member. I don't know what your initial reaction will be, but I think this is wonderful news for you ---- a true home, active mentoring, a lot more protection, and a lot more investment in your career. I have no way to protect you in my department or to provide the type of environment you need. I would be happy to continue to advise you as before, but this is a move you must make for your own career success. I'm free to discuss any aspect of this with you.

BK

Bruce C. Kone, M.D., FACP, FCP, FAHA, FASN, FAAAS
The James T. and Nancy B. Willerson Chair
Chairman, Department of Medicine
Professor of Internal Medicine and of Integrative Biology
and Pharmacology
The University of Texas Medical School at Houston
6431 Fannin, MSB 1.150
Houston, TX 77030

TEL: 713 500-6500 FAX: 713 500-6497

http://www.uth.tmc.edu/schools/med/imed/chairman.htm

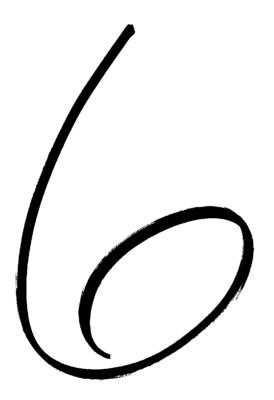
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Administrative Assistant: Michelle Smith (Nancy.M.Smith@uth.tmc.edu)

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9/12/10 5:27 PM



From:

Rayburn, John

Sent:

Monday, April 02, 2007 12:51 PM

To: Subject: King, Terri M Request to Interview

Attachments:

uthsc h logo.jpg



Hello Dr. King,

I am the EO Advisor for the University and I am currently investigating a complaint. I was given your name as a possible witness.....you are not named in the complaint. I would like to schedule a brief meeting with you to confidentially discuss any pertinent information or knowledge you may have regarding the complaint. Can we schedule a brief meeting this week? (I am available this week until close of business on Wednesday.) Please advise.

J.T. Rayburn
Equal Opportunity Advisor
University of Texas Health Science Center at Houston
Texas Medical Center
7000 Fannin, Ste. 150
Houston, TX 77030
713.500.3079
713.500.3124 (fax)

From:

Rayburn, John

Sent:

Monday, April 02, 2007 1:21 PM

To:

King, Terri M

Subject:

RE: Request to Interview

Attachments:

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Ok. The receptionist will call me when you get here. Thanks!

J.T. Rayburn
Equal Opportunity Advisor
University of Texas Health Science Center at Houston
Texas Medical Center
7000 Fannin, Ste. 150
Houston, TX 77030
713.500.3079
713.500.3124 (fax)

From: King, Terri M

Sent: Monday, April 02, 2007 1:20 PM

Fo: Rayburn, John

Subject: RE: Request to Interview

I can come down now - I just finished lunch and haven't started anything up just yet :-)

tking

From: Rayburn, John

Sent: Monday, April 02, 2007 1:19 PM

To: King, Terri M

Subject: RE: Request to Interview



Great! You pick the time. This should only take about 15 minutes unless you have A LOT to share. What time is best for you?

J.T. Rayburn
Equal Opportunity Advisor
University of Texas Health Science Center at Houston
Texas Medical Center
7000 Fannin, Ste. 150
Houston, TX 77030
713.500.3079
713.500.3124 (fax)

From: King, Terri M

Sent: Monday, April 02, 2007 1:14 PM

To: Rayburn, John

Subject: RE: Request to Interview

Yes, I am in the tower today, but I don't have a place to meet - I can come down to $\mathcal{H}\mathcal{R}$

tking

From: Rayburn, John

Sent: Monday, April 02, 2007 1:13 PM

Fo: King, Terri M

Subject: RE: Request to Interview



Yes, that would be great. Am I understanding that you are at UCT? If so, do you have a place to meet....or would you prefer to come down to HR (ste. 150)?

J.T. Rayburn
Equal Opportunity Advisor
University of Texas Health Science Center at Houston
Texas Medical Center
7000 Fannin, Ste. 150
Houston, TX 77030
713.500.3079
713.500.3124 (fax)

From: King, Terri M

Sent: Monday, April 02, 2007 1:12 PM

To: Rayburn, John

Subject: RE: Request to Interview

Hi Mr Rayburn -

My schedule is pretty clear today and tomorrow AM (my two days in the UCT) - would it be possible to arrange something this afternoon?

tking

From: Rayburn, John

Sent: Monday, April 02, 2007 12:51 PM

To: King, Terri M

Subject: Request to Interview



Hello Dr. King,

I am the EO Advisor for the University and I am currently investigating a complaint. I was given your name as a possible witness.....you are not named in the complaint. I would like to schedule a brief meeting with you to confidentially discuss any pertinent information or knowledge you may have regarding the complaint. Can we schedule a brief meeting this week? (I am available this week until close of business on Wednesday.) Please advise.

J.T. Rayburn
Equal Opportunity Advisor
University of Texas Health Science Center at Houston
Texas Medical Center
7000 Fannin, Ste. 150
Houston, TX 77030
713.500.3079
713.500.3124 (fax)



Clear Day

King, Terri M

From:

Rayburn, John

Sent:

Tuesday, April 24, 2007 3:12 PM

To:

King, Terri M

Subject:

RE:

Signed By: john.rayburn@uth.tmc.edu

Works fine. See you then. (Friday, May 4 at 9:30)

x The University of Texas Health Science Center at

Houston

J.T. Rayburn Equal Opportunity Advisor University of Texas Health Science Center at Houston Texas Medical Center 7000 Fannin, Ste. 150 Houston, TX 77030 713.500.3079 713.500.3124 (fax)

From: King, Terri M

Sent: Tuesday, April 24, 2007 3:11 PM

To: Rayburn, John Subject: RE:

Let's say 9:30 on Friday (5/3) and I will just drive directly to UCT on my way into work - does that work for you?

tking

From: Rayburn, John

Sent: Tuesday, April 24, 2007 3:08 PM

To: King, Terri M Subject: RE:



I'm available all day Friday, you name the time. Also, if you are at another location, I'll be happy to come to your location ...not a problem at all. Please advise

J.T. Rayburn
Equal Opportunity Advisor
University of Texas Health Science Center at Houston
Texas Medical Center
7000 Fannin, Ste. 150
Houston, TX 77030
713.500.3079
713.500.3124 (fax)

From: King, Terri M

Sent: Tuesday, April 24, 2007 2:39 PM

To: Rayburn, John Subject: RE:

Friday is good

tking

From: Rayburn, John

Sent: Tuesday, April 24, 2007 12:31 PM

To: King, Terri M Subject: RE:

We can talk on May 3 if you are comfortable with a telephone meeting. (Unless you definitely want to meet in person.) Otherwise, how about Friday, may 4?



J.T. Rayburn
Equal Opportunity Advisor
University of Texas Health Science Center at Houston
Texas Medical Center
7000 Fannin. Ste. 150
Houston, TX 77030
713.500.3079
713.500.3124 (fax)

From: King, Terri M

Sent: Tuesday, April 24, 2007 12:28 PM

To: Rayburn, John **Subject:** RE:

Yikes - I wasn't looking at the calendar and didn't realize that next Tuesday was already May - I will be out of the office on May 1-2. But I can make an appt for that Thursday. May 3

5/24/2007

tking

From: Rayburn, John

Sent: Tuesday, April 24, 2007 12:27 PM

To: King, Terri M **Subject:** RE:



How about 3:00 on Tuesday, May 1?

J.T. Rayburn
Equal Opportunity Advisor
University of Texas Health Science Center at Houston
Texas Medical Center
7000 Fannin, Ste. 150
Houston, TX 77030
713.500.3079
713.500.3124 (fax)

From: King, Terri M

Sent: Tuesday, April 24, 2007 12:20 PM

To: Rayburn, John Subject: RE:

Let's do Tuesday, since I will be at UTC for that day - what time works for you? I have a standing appt from 12:30 to 2:30. Other than that I am free.

tking

From: Rayburn, John

Sent: Tuesday, April 24, 2007 9:00 AM

To: King, Terri M Subject: RE:



I should be completed by end of this week. Do you want to set something up for next week? Tues, Wed or

Clear Day Page 4 or 6

Frid?

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7000 Fannin, Ste. 150
Houston, TX 77030
713.500.3079
713.500.3124 (fax)

From: King, Terri M

Sent: Monday, April 23, 2007 1:04 PM

To: Rayburn, John Subject: RE:

That sounds fine - what is your timeline?

tking

From: Rayburn, John

Sent: Monday, April 23, 2007 12:56 PM

To: King, Terri M Subject: RE:



Ok, then I will report out as planned. If you like, we can schedule a meeting again to discuss the other.

J.T. Rayburn
Equal Opportunity Advisor
University of Texas Health Science Center at Houston
Texas Medical Center
7000 Fannin, Ste. 150
Houston, TX 77030
713.500.3079
713.500.3124 (fax)

From: King, Terri M

Sent: Monday, April 23, 2007 12:27 PM

To: Rayburn, John Subject: RE:

Not about that particular investigation, but about the situation overall. It involves some information extraneous to the specifics to that investigation, which is why I didn't want to mention it during our previous interview.

Clear Day rage 3 or c

However, I do believe it is information that HR should be made aware of not only for the protection of classified staff and students, but also for university resources.

I will take your advice on how to proceed

tking

From: Rayburn, John

Sent: Monday, April 23, 2007 12:25 PM

To: King, Terri M Subject: RE:



Hello Dr. King,

I've completed my investigation, but am in the middle of reporting out. Is there anything that needs to be discussed prior to me reporting out? (i.e. Is there anything additional that you need me to know?)

J.T. Rayburn
Equal Opportunity Advisor
University of Texas Health Science Center at Houston
Texas Medical Center
7000 Fannin, Ste. 150
Houston, TX 77030
713.500.3079
713.500.3124 (fax)

From: King, Terri M

Sent: Monday, April 23, 2007 11:09 AM

To: Rayburn, John

Subject:

If the case that we discussed is closed, can you and I have an additional conversation?

Terri M. King, Ph.D.

Terri M. King, Ph.D.
Department of Pediatrics
Divisions of Medical Genetics and Developmental Pediatrics
University of Texas - Houston Medical School
6431 Fannin, MSB 3.149
Houston, Texas 77030
Phone - 713-500-5659
Pager - 713-506-0066
Fax - 713-500-5689

E-mail - Terri.M.King@uth.tmc.edu

5/24/2007

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falsification.

The difference between Science and Advocacy is that scientists expose their ideas to



From: Rayburn, John

Sent: Friday, May 04, 2007 11:19 AM

To: King, Terri M

Subject: Our discussion...



Hello Terri,

I've consulted with my director and we have determined your concern as it relates to employees feeling like they need to alter data because of Dr. Milewicz's behaviors is a compliance issue. We recommend you contact either Karen Parsons at 7.500.3310 or call the Compliance Hotline at 1.888.472.9868. You can make these reports anonymously.

J.T. Rayburn
Equal Opportunity Advisor
University of Texas Health Science Center at Houston
7000 Fannin, Ste. 150
Houston, TX 77046
713.500.3079
713.500.3124 (fax)

crom:

King, Terri M

Sent:

Wednesday, May 09, 2007 10:52 AM

To:

Parsons, Karen K

Subject:

RE: Follow-up to our conversation - 5/4

For the moment -

tking

----Original Message----

From: Parsons, Karen K

Sent: Wednesday, May 09, 2007 10:47 AM

To: King, Terri M

Subject: RE: Follow-up to our conversation - 5/4

Thanks; would you prefer to make this an anonymous report?

Karen K. Parsons, J.D.

Director, Institutional Compliance

Office of Legal Affairs and Institutional Compliance The University of Texas Health Science Center at Houston P.O. Box 20036 Houston, Texas 77225 Phone 713/500-3310 Fax 713/500-0326 email Karen.K.Parsons@uth.tmc.edu

----Original Message----

From: King, Terri M

Sent: Sunday, May 06, 2007 10:42 AM

To: Parsons, Karen K

Subject: Follow-up to our conversation - 5/4

Importance: High

Ms Parsons -

There are two additional individuals that can provide information related to the current level of intimidation in Dr. Milewicz's laboratory.

The first is Van Tran-Fadulu (Van.Tran.1@uth.tmc.edu) who is the Genetic Counselor in the Division.

The second is Lisa Vincent (genesnscience@yahoo.com) who is a very recent PhD graduate (12/2006) from that laboratory. I served on her thesis committee.

Please let me know if there is any additional information that you need.

Terri King

Terri M. King, Ph.D.

Department of Pediatrics

Divisions of Medical Genetics and Developmental Pediatrics University of Texas - Houston

Medical School

6431 Fannin, MSB 3.149

Houston, Texas 77030

Phone - 713-500-5659

Pager - 713-506-0066

Fax - 713-500-5689

E-mail - Terri.M.King@uth.tmc.edu

From: King, Terri M

Sent: Sunday, May 06, 2007 10:42 AM

To: Parsons, Karen K

Subject: Follow-up to our conversation - 5/4

Importance: High

Ms Parsons -

There are two additional individuals that can provide information related to the current level of intimidation in Dr. Milewicz's laboratory.

The first is Van Tran-Fadulu (Van.Tran.l@uth.tmc.edu) who is the Genetic Counselor in the Division.

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Please let me know if there is any additional information that you need.

Terri King

Terri M. King, Ph.D.
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Page 1 of 1

King, Terri M

From: King, Terri M

Sent: Wednesday, May 16, 2007 4:41 PM

To: Parsons, Karen K

Subject: Follow-up on Conversation 5/14

Hi Karen -

Here are some names of individuals who can provide additional or supportive information regarding our conversation on 5/14 -

Alteration of data in response to direct or indirect pressure / intimidation (In addition to Van Tran and Lisa Vincent)

- Dawn Simmons (dawn.m.simmons@uth.tmc.edu)
- Judy Kao (Yachu.J.Kao@uth.tmc.edu)
- Andrea Lafont (Andrea L. Lafont@uth.tmc.edu)
- Debra Wallis (JT in Human Resources has her contact information)

Fiscal management of projects (e.g. using monies from one project to pay for activies of another project)

Norma Adams (JT in Human Resources has her contact information)

General harassment as well as harassment of protected classes (e.g., racial, sexual, religious)

- Norma Adams (JT in Human Resources has her contact information)
- Erin Nies (eenies@mdanderson org)

I am still working through my files to identify additional names.

Let me know if you need any

Terri M. King, Ph.D.

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The difference between Science and Advocacy is that Scientists expose their ideas to falsification.